

### **Remarks**

Claims 1-39 are presented for the Examiner's review and consideration. Herein, claims 1-2, 9, 11-13, and 19-20 have been amended; claims 38-39 have been added; and claims 3 and 21 have been canceled. Applicant believes the claim amendments and the accompanying remarks, herein, serve to clarify the present invention and are independent of patentability. No new matter has been added.

#### **35 U.S.C. §102(e) Rejection - Coates**

Claims 1-37 were rejected under 35 U.S.C. §102(e) as being anticipated by Coates (5,035,699) ("Coates"). For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

Coates discloses a surgical device for accurately positioning and cutting a patellar groove in a resected distal femur to receive a patellar track portion of a prosthesis, including a guide element adapted to fit over the distal end of a resected femur... (Abstract). With reference to Fig. 1 of Coates, end 14 is adapted to fit on the posterior side of the resected femur and consists of 2 arms adapted to fit over the medial and lateral condyles of the femur. (Col. 2, lns. 31-33). The central portion of the cutting guide 10 consists of an elongated opening 23 which exposes at least the distal and anterior aspects of the resected femur so that a patellar groove may be cut therein. (Id).

Thus Coates is directed to a cutting guide which is aligned by being positioned on a resected femur. Coates does not address how the femur is resected, however at the time of Coates, the commonly accepted method was through the use of an intramedullary rod. There is no suggestion in Coates of an alternative method.

In contrast, the present invention discloses method[s] of performing surgery, and instruments, implants, and other surgical implements that can be used in surgery. The surgery may be of any desired type. (§[0002]). The surgery may be performed on any desired joint in a patient's body. Id.

When the femoral cuts are to be made on the distal end portion 124 of the femur 126, the femoral cutting guide 750 is connected to the distal end of the femur. (§[0490]).

...extramedullary instrument could be employed. If desired, the base 1376 could be pinned directly to the femur in a manner analogous to the cutting guide 800 (Fig. 54). (Id). Alternatively, the base 1376 could be positioned on the femur using a computer navigation system. (Id).

It is contemplated that emitters, receivers, and/or reflectors of computer navigation systems could be pinned or otherwise attached onto the femur 126 and tibia 214 to provide cutting positions and to facilitate ligament balancing through relatively small incisions. (§[0288]). The computer navigation system may utilize three or four separate registers which have optical feedback to a central unit. (Id). The computer navigation system may utilize electromagnetic or photo-optical feedback.

It is contemplated that the imaging of the knee portion 76 of the patient's leg 70 may be done preoperatively, on an out-patient basis. (§[0556]). The implant 950, which has been shaped to conform to the space between the surfaces 958 and 960, may then be moved to an operating room for insertion into a patient during the surgical procedure. (Id).

...Discussed throughout this specification, the present invention includes disposable surgical implants and instruments. (§[0706]). One advantage of the disposable system is that the disposable cutting blocks could easily be modified for new or updated instrumentation or for customized instrumentation. (§[0712]).

Thus, the present invention provides for attachment of a cutting guide to a femur without first resecting the femur, and without connection to an EM or IM rod. Moreover, the present invention provides for disposable cutting blocks, which, because they are made from a low cost, easy to manufacture polymer, may be modified for each use to accommodate custom requirements.

As discussed above, Coates does not provide a means for connecting or aligning a cutting guide without first resecting the knee for a total knee replacement. Of course, alignment must be performed for the resection, and no means are disclosed for such. Notwithstanding this, it is clear that the cutting guide of Coates is not aligned with respect to knee, generally, but to the resection, only. Thus, Coates does not provide a means of positioning a cutting guide without a prior resection of the femur, and the anterior section, in particular. In addition, the use of intramedullary alignment is implicit in Coates. Further, there is no discussion of disposable instrumentation in Coates, nor of the attendant benefits of same.

Claim 1 recites, *inter alia*, positioning a cutting guide on a surface of a distal end portion of the femur, positioned free of an extramedullary or intramedullary rod, and positioned using navigation references derived from the surface of the bone to be cut, and not derived from an intramedullary device.

Claim 13 recites, *inter alia*, a disposable cutting guide member fabricated from a polymeric material and designed for a single use, having a body dimensioned for attachment to a surface of an end portion of the bone free of an extramedullary or intramedullary alignment rod, and wherein said cutting guide, being both polymeric and disposable, is readily modified in successive iterations for new or customized instrumentation.

Claim 19 recites, *inter alia*, fabricating a disposable cutting guide, designed for a single use from a polymeric material, and modified for updated or customized instrumentation, and positioning the cutting guide through the incision and on a side surface of an end portion of the first bone before the anterior surface of said first bone is resected, using navigation references derived from the surface of the bone to be cut, and not derived from an intramedullary device.

Accordingly, Applicant respectfully submits that independent claims 1, 13, and 19 are patentable over Coates. Claims 3 and 21 are canceled. As claims 2 and 4-12 depend from claim 1; claims 14-18 depend from claim 13; and claims 20 and 22-29 depend from claim 19, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the remaining dependent claims are allowable over Coates at least for the same reasons.

In light of the foregoing, Applicant requests reconsideration and withdrawal of this section 102 rejection.

35 U.S.C. §102(e) Rejection - Haines

Claims 1-37 were rejected under 35 U.S.C. §102(e) as being anticipated by Haines et al. (6,056,754) (“Haines”). For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

In Haines, a femur is resected by means of pattern plates having a cutting path with at least two continuous, non-coplanar guide surfaces. (Abstract). The cutting path has a similar profile to the interior profile of a femoral prosthesis. (Id). The cutting path guides a reciprocating, oscillating, or rotating cutting tool along a path for removing material from some or all of the distal femur to accept a distal femoral prosthesis. (Id).

The apparatus of [Haines] comprises a number of components including a positioning apparatus, a pattern apparatus and a cutting apparatus. (Col. 6, lns. 35-37). Pattern plates 32 include fixation apertures 34 extending therethrough for accepting fixation means, as will hereinafter be described, for affixing the pattern plates 32 to a bone. (Col. 8, lns. 59-61).

The positioning body 120 comprises a frame 122 having sides 124, bottom 126 and top 128 arranged to form a frame having a rectangular aperture defined therewithin. (Col. 10, lns. 19-22).

The alignment apparatus 180 interconnects with the positioning body 120 by means of alignment guide body 182 which is a U-shaped member having sides 184 and a bottom 186. (Col. 11, lns. 2-5). The alignment guide body 182 is sized to fit within the rectangular aperture formed within the positioning body 120. (Id). The alignment plate 192 further includes rod guide aperture 197 which receives rod guide bolt 196 therethrough to interconnect the alignment plate 192 with the IM rod guide 210... (Col. 11, lns. 26-29).

The IM rod guide 210 includes IM rod aperture 212 for receiving an IM rod therethrough. (Col. 11, lns. 33-34). The IM rod guide 210 is interconnected at a forward end with the alignment plate 192 by means of plate attachment aperture 214 on the rod guide 210 which receives rod guide bolt 196 therein after such bolt 196 passes through the alignment plate 192 to secure the

rod guide 210 in a pivoting relationship with respect the alignment plate 192 at forward ends of the rod guide 210 and the alignment plate 192. (Id).

The alignment plate 192 further includes a printed angular rotation scale which indicates the degree of angular rotation between the rod guide 220 and the alignment apparatus, and hence the angular rotation between the IM rod and the positioning body 120. (Col. 11, lns. 51-55). After such alignment is determined, it can be locked into place by tightening down rod guide lock bolt 200. (Id). Thereafter, with such angular rotation fixed, the pattern apparatus 30 can be positioned with respect to the bone to cut, and the positioning apparatus 110 can be removed from interconnection with the IM rod and the pattern apparatus 30, the IM rod removed from the bone, and bone cutting can be initiated. (Id).

Various fixation means, including those known in the art, can be used to fix the pattern plate or plates to the femur or other bone to be cut. FIG. 11 shows a preferred fixation means, generally indicated at 260. (Col. 12, lns. 23-25). The fixation means 260 includes a spike plate 264 carrying on one side thereof a spike or spikes 262 for contacting, and even extending into, bone 261. (Id).

Thus Haines discloses an intramedullary rod (IM rod) which serves to reference the positioning body, whereupon the latter orients the alignment guide. The alignment guide is used to position the pattern plates, which are in turn affixed to bone using conventional means. Once the pattern plates are affixed, the IM rod is removed and the bone cuts are carried out.

Accordingly, while Haines does not appear to require a resection of the anterior surface of the bone prior to positioning a cutting guide, as in Coates, Haines none the less requires an intramedullary rod, with its attendant drawbacks, including trauma to bone tissue, increased bleeding, and an increased potential for fat emboli. Further, as in Coates, Haines does not disclose a customized disposable cutting guide.

Accordingly, Applicant respectfully submits that independent claims 1, 13, and 19 are patentable over Haines. Claims 3 and 21 are canceled. As claims 2 and 4-12 depend from claim 1; claims 14-18 depend from claim 13; and claims 20 and 22-29 depend from claim 19, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant

respectfully submits that the remaining dependent claims are allowable over Haines at least for the same reasons.

In light of the foregoing, Applicant requests reconsideration and withdrawal of this section 102 rejection.

#### New Claims

Claim 38 has been added to specify, *inter alia*, that the cutting guide of claim 1 is disposable. Claim 39 has been added to specify, *inter alia*, means of aligning the cutting guide of claim 13. Support for these claims may be found in the discussion of the present invention, in support of arguments pertaining to Coates, above.

#### Conclusion

In the light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fees are believed to be due. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 780-A03-012C).

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'P. Bianco', with a large, sweeping flourish above the name.

Paul Bianco, Reg. #43,500

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